DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N–0319]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey about knowledge, perceptions, attitudes, and practices related to dietary supplements and food.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health and Diet Survey

The authority for FDA to collect the information derives from the authority of the Commissioner of Food and Drugs, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)). The Health and Diet Survey will provide FDA information about consumers' knowledge, perceptions, attitudes, and practices related to dietary supplements and food. A nationally representative sample of 2,000 adults in the 48 contiguous States and the District of Columbia will be selected at random and interviewed by telephone. Participation will be voluntary. The survey will collect information about: (1) Prevalence, experience, and purposes of use of dietary supplements; (2) knowledge of health benefits, health risks, and regulation of

dietary supplements; (3) sources of dietary supplement information; (4) perceptions of dietary supplement labels; (5) replacement and combination use of supplements and drugs; (6) adverse experience with dietary supplements; (7) children's and teenagers' use of dietary supplements; (8) knowledge of diet-health relationships; (9) dietary management practices; and (10) use of food labels.

Some of the questions to be asked (items 8 through 10 listed in the previous paragraph) replicate the ones asked in the 1995 Health and Diet Survey. Responses to these questions will help FDA identify and measure any changes in consumer knowledge, perceptions, attitudes, and practices with regard to diet, health, and use of food labels. The information will also help the agency evaluate the effectiveness of the Nutrition Labeling and Education Act of 1990 in promoting the public health.

The agency will use the other questions in the proposed survey to enhance its understanding of consumer knowledge, perceptions, attitudes, and practices regarding dietary supplements. Subsequent to the enactment of the Dietary Supplement Health and Education Act of 1994, the consumption of dietary supplements in the United States has been increasing. FDA needs current, timely, and policy-relevant consumer information to help it identify needs for and develop consumer education programs and regulatory policies to ensure safe and appropriately labeled supplement products. The survey will help the agency measure prevalence and distribution of consumer knowledge, perceptions, attitudes, and practices. This information can be used to understand and describe the consumer environment that is the intended target of labeling and education initiatives.

FDA estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview	9	1	9	1.5	13.5
Pretest	9	1	9	0.5	4.5
Screener	4,200	1	4,200	0.02	84
Survey	2,000	1	2,000	0.5	1,000
Total					1,102

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with previous consumer surveys. Prior to the administration of the survey, the agency plans to conduct a series of nine cognitive interviews and a series of nine pretests to ensure the quality of the survey. Cognitive interviews will help the agency understand respondent comprehension of the meanings of questions and words, and